through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 783–3238.

Dated: March 15, 1995.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–6861 Filed 3–20–95; 8:45 am]

BILLING CODE 4163–19–P

Food and Drug Administration

[Docket No. 95G–0039]

Degussa Corp.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Degussa Corp. has filed a petition (GRAS 2419) proposing that hydrophobic silica, prepared by the hydrophobization of silicon dioxide with dichlorodimethyl-silane, be affirmed as generally recognized as safe (GRAS) as an anticaking/free-flow agent in vitamin preparations for animal feed.

DATES: Written comments by June 5, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: J. D. McCurdy, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1731.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 201(s), 409(b)(5) (21 U.S.C. 321(s) and 348(b)(5)) and the regulations for affirmation of GRAS status in § 570.35 (21 CFR 570.35), notice is given that Degussa Corp., c/o Counsel for Petitioner, Jerome H. Heckman, Keller, and Heckman, 1001 G St. NW., Suite 500 West, Washington, DC 20001, has filed a petition (GRASP 2419) proposing that hydrophobic silica, prepared by the hydrophobization of silicon dioxide with dichlorodimethyl-silane, be affirmed as GRAS as an anticaking/free-flow agent in vitamin preparations for animal feed.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 570.30 (21 CFR 570.30) and 570.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Interested persons may, on or before June 5, 1995, review the petition and file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 8, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–6918 Filed 3–20–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Arthritis Advisory Committee. This meeting was announced in the **Federal Register** of February 17, 1995 (60 FR 9338). This amendment is being made to announce the cancellation of the open committee discussion portion of the meeting and adjustment of the starting time. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Isaac F. Roubein, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Arthritis Advisory Committee, code 12532.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 17, 1995 (60 FR 9338), FDA announced that the Arthritis Advisory Committee would hold a meeting on March 27, 1995.

On page 9338, column 2, the ''*Date, time, and place*'' portion is amended to read as follows:

Date, time, and place. March 27, 1995, 9 a.m., Holiday Inn—Silver Spring, Silver Room, 8777 Georgia Ave., Silver Spring, MD.

On page 9338, column 2, the ''*Type of meeting and contact person*'' portion is amended to read as follows:

Type of meeting and contact person. Open public hearing, 9 a.m. to 10 a.m., unless public participation does not last that long; closed committee deliberations, 10 a.m. to 4 p.m.; Isaac F. Roubein, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Arthritis Advisory Committee, code 12532.

Dated: March 16, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–7068 Filed 3–17–95; 3:46 pm]

BILLING CODE 4160–01–F

Advisory Committee Meetings; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Nonprescription Drugs Advisory Committee. This meeting was announced in the **Federal Register** of February 17, 1995 (60 FR 9335 at 9336). The amendment is being made to announce the cancellation of the joint session with the Dermatologic and Ophthalmic Drugs Advisory Committee; the cancellation of the session with

Pulmonary-Allergy Drugs Advisory Committee representation; the addition of joint sessions with the Gastrointestinal Drugs Advisory Committee and the Arthritis Advisory Committee; the addition of closed sessions to the agenda and consequent adjustment in times; and the correction of the new drug application (NDA) number announced under open committee discussion scheduled for March 28, 1995. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Lee L. Zwanziger or Liz Ortuzar, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 17, 1995, FDA announced that the Nonprescription Drugs Advisory Committee would hold a joint meeting with the Dermatologic and Ophthalmic Drugs Advisory Committee, followed by a session with the Pulmonary-Allergy Drugs Advisory Committee representation, and a joint meeting with the Arthritis Advisory Committee on March 27 and 28, 1995.

On page 9336, in column 2, the ''*Date, time, and place*'' portion of this meeting is amended as follows:

Date, time, and place. March 27, 1995, 1 p.m., and March 28, 1995, 8 a. m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

On page 9336, in column 2, the ''*Type of meeting and contact person*'' portion of this meeting is amended as follows:

Type of meeting and contact person. Open committee discussion, March 27, 1995, 1 p.m. to 3 p.m.; open public hearing, 3 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5 p.m.; closed committee deliberations for the Nonprescription Drugs Advisory Committee only, 5 p.m. to 6 p.m.; open committee discussion, March 28, 1995, 8 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12 m., unless public participation does not last that long; joint closed committee deliberations, 12 m. to 12:30 p.m.; open committee discussion, 12:30 p.m. to 4 p.m.; Lee L. Zwanziger or Liz Ortuzar, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541.

On page 9336, in column 2, the ''*General function of the committees*'' portion is amended as follows:

General function of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Gastrointestinal Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in gastrointestinal diseases. The Arthritis Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

On page 9336, in column 3, the ''*Open committee discussion*'' portion is amended as follows:

Open committee discussion. On March 27, 1995, the Nonprescription Drugs Advisory Committee and the Gastrointestinal Drugs Advisory Committee will discuss SmithKline Beecham's NDA 20–238 for over-the-counter (OTC) Tagamet® (cimetidine) tablets for the treatment of heartburn. On the morning of March 28, 1995, the Nonprescription Drugs Advisory Committee and the Arthritis Advisory Committee will discuss data relevant to NDA 20–516 for ibuprofen suspension (Motrin®, McNeil Consumer Products) for the treatment of fever and of pain in children between 2 and 12 years of age. On the afternoon of March 28, 1995, the Nonprescription Drugs Advisory Committee and the Arthritis Advisory Committee will discuss recommendations regarding appropriate OTC indication(s) for muscle relaxants, OTC dose(s) and duration of use, safety profiles, abuse potential, and pharmacokinetic information.

After the ''*Open committee discussion*'' portion, a ''*Closed committee deliberations*'' portion is added as follows:

Closed committee deliberations. On March 27 and 28, 1995, the committees will discuss trade secret and/or confidential commercial information relevant to pending investigational new drug applications. These portions of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600

Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: March 16, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95–7069 Filed 3–17–95; 3:46 pm]

BILLING CODE 4160–01–F

Health Care Financing Administration

Office of Research and Demonstrations; Statement of Organization, Functions, and Delegations of Authority

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Health Care Financing Administration (HCFA), (**Federal Register**, Vol. 59, No. 60, pp. 14642–43, dated Tuesday, March 29, 1994) is amended to reflect various changes resulting from the streamlining and reorganization of the Office of Research and Demonstrations (ORD).

These changes abolish the current ORD substructure which consists of three subordinate offices and one staff, and establish a new substructure which consists of four subordinate offices and two subordinate staffs. These changes will realign all current ORD functions into the following activity areas: information dissemination; financial, administrative, and procurement support; state health reform demonstrations; payment, delivery, and financing research and demonstrations; beneficiary related research and demonstrations; and ORD program support activities.

The specific changes to Part F are:

- Section F.10.C.3.a, through Section F.10.C.3.c.(2) is deleted in its entirety and replaced by the following revised functional statements. The new sections F.10.C.3.a through F.10.C.3.f.(2) read as follows:

A. Dissemination Staff (FKB–2)

- Produces and distributes ORD publications, such as the Health Care Financing Review, Status Report, Publications Catalog, and Reports to Congress.
- Coordinates ORD's input for the annual HCFA Report to Congress.
- Markets materials, including electronically produced data and publications to consumers, customers and other individuals or organizations.
- Develops new dissemination strategies that encourage the adoption and diffusion of innovations in health care financing and delivery.
- Manages internal and external inquiries.
- Provides conference support.
- Provides technical and editorial support services.
- Coordinates with the Government Printing Office and the National Technical Information Service.
- Maintains resource material for internal use.
- Develops and disseminates internal communications and operational procedures.
- Reviews, coordinates and serves as liaison for administrative correspondence.

B. Financial, Administrative and Procurement Staff (FKB–3)

- Plans, directs and implements a comprehensive office-wide human resources and employee development program.
- Coordinates ORD's section of the HCFA strategic plan.
- Coordinates the Federal Managers Financial Integrity Act.
- Plans, directs and implements office-wide facilities and property management programs.
- Plans, directs and implements comprehensive office-wide budget and financial management programs.
- Coordinates grants, contracts, cooperative agreements and waiver activities.
- Plans and develops ORD's Acquisition Planning Document.
- Develops and implements the ORD Waiver Compendium.
- Manages Freedom of Information and Privacy Act issues.

C. Office of State Health Reform Demonstrations (FKB4)

- Conducts research, demonstrations and evaluations to support the development and implementation of State health and welfare reform demonstrations.
- In partnership with other HCFA bureaus and DHHS offices, directs the